10-2-86

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 07-10-86 OUT 10-01-86

Dennis G. Guse 10-2-86

Reviewed By Dennis G. Guse Date 10-01-86

EPA Reg. No. or File Symbol 777-32, -44, -53; 675-15, -43, -45

EPA Petition or EUP No. None

Date Division Received 07-09-86

Type Product Virucide Vs. HTLV-III/LAV (AIDS) Virus

Data Accession No(s). None

Product Manager 31 (Lee)

Product Name Various Lehn & Fink/National Laboratories products

Company Name Lehn & Fink Products/National Laboratories

Submission Purpose Resubmission of test protocol for evaluating disinfectants against AIDS virus

Type Formulation Various liquids & pressurized sprays

Active Ingredient(s):	%
Various	Various

200.0 Purpose of Protocol

To quantitatively evaluate the inactivation of HTLV-III/LAV (AIDS) virus on inanimate hard surfaces treated with disinfectant products.

200.1 Background

Refer to the review by TSS (Efficacy), dated 05-28-86, of a previously submitted AIDS virus test protocol prepared by Bionetics Research for the same company.

The current submission is in response to the deficiencies cited in the previous review.

201.0 Brief Description of Protocol

"Disinfectant Inactivation of HTLV-III (Protocol TCLF-II)" by Lehn & Fink Products Group.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 777-32, -44, -53; 675-15, -43, -45

Date Division Received 07-09-86

Data Accession No(s). None

Product Manager No. 31 (Lee)

Product Name Various Lehn & Fink/National Laboratories products

Company Name Lehn & Fink Products/National Laboratories

202.0 Evaluation of Protocol

202.1 General Comments

The proposed protocol cannot be accepted for determination of the virucidal activity of a disinfectant against the AIDS virus on inanimate surfaces because no data were submitted to show quantitative survival of the virus on a hard surface carrier before and after drying under representative conditions as indicated in the review of a previously submitted protocol.

Refer to the previous review for the requirements as to certain information and specific data which must be submitted before any protocol can be considered from any applicant for testing of disinfectants against the AIDS virus.

202.2 Specific Comments

a. Submitted Data/Information

1. Test Virus

The submitted identification and description of the AIDS virus cultures proposed for testing, including literature citations, propagation methods, concentration procedures, inoculum composition, and anticipated titer, appear adequate.

2. Quantitative Assay of Infective Virus

The submitted description of the quantitative method proposed for assay of the infective AIDS virus, including literature citations, host cell system, and assay procedure, appear adequate.

3. Controlled Drying Data

No data were submitted.

The submitted proposal to evaluate quantitative survival of two AIDS virus cultures, as specified above, before and after drying under controlled conditions are not adequate.

The viral inocula must be exposed to air drying, as described in the protocol, in non-humidified air for at least 20 minutes at 35-37°C and 45 minutes at room temperature (20-25°C).

4. Literature References

The submitted copies of cited literature fulfill the request in this regard.

b. Submitted Revised Protocol

1. The described procedure for obtaining concentrated (10,000X, 1,000X) virus stocks appears adequate.

2. The submitted proposal for drying the virus inoculum on a test surface appears adequate, except that the procedure must be modified to include the conditions indicated 202.2(a)(3) above.

Under the above conditions, a virus titer of at least 10^4 ID-50 must be recovered from the surface after drying.

3. The described proposals for applying liquid or spray disinfectants to the dried virus film appear adequate.

4. The described procedure for determination and reporting of virus infectivity and/or cytotoxicity for the virus-disinfectant mixtures, untreated virus control, and cytotoxicity control appears adequate.

5. In the proposed protocol, an additional control must be included in which serial dilutions of the untreated virus inoculum (virus control) are mixed with the corresponding serial dilutions of the disinfectant (cytotoxicity control), and the resulting mixtures of dilutions are employed for infection of target cells and subsequent assay procedures. There should be no significant difference between this control and the combined results of the positive (untreated) virus control and the disinfectant (cytotoxicity) control. This is necessary to show the presence or absence of residual virucidal activity of the diluted disinfectant during the manipulation of samples.

6. Evaluation of the proposed protocol cannot be completed until the remainder of the required preliminary data/information indicated in 202.2(a) above are submitted and reviewed.